

ORAL ARGUMENT SCHEDULED FOR MARCH 21, 2025

Docket No. 24-1151

Consolidated with Docket Nos. 24-1185, 24-1182, 24-1202, 24-1237

**IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT**

TEXAS CHEMISTRY COUNCIL, et al.,

Petitioners,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY, et al.,

Respondents,

OLIN CORPORATION, et al.,

Intervenors.

*On Petition for Review of Final Action by the
U.S. Environmental Protection Agency*

**JOINT REPLY BRIEF OF PETITIONERS TEXAS CHEMISTRY
COUNCIL, AMERICAN CHEMISTRY COUNCIL, AMERICAN FUEL &
PETROCHEMICAL MANUFACTURERS, AND AMERICAN
PETROLEUM INSTITUTE**

Rafe Petersen
Meaghan Colligan Hembree
HOLLAND & KNIGHT LLP
800 17th Street N.W.
Suite 1100
Washington, D.C. 20006
Rafe.Petersen@hklaw.com
Meaghan.Colligan@hklaw.com
Tel.: (202) 419-2481

*Attorneys for Petitioners
Texas Chemistry Council and
American Chemistry Council*

David Y. Chung
Warren Lehrenbaum
CROWELL & MORING LLP
1001 Pennsylvania Avenue N.W.
Washington, D.C. 20004
DChung@crowell.com
WLehrenbaum@crowell.com
Tel.: (202) 624-2587

*Attorneys for Petitioners American
Fuel & Petrochemical Manufacturers
and American Petroleum Institute*

TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES	v
GLOSSARY OF ABBREVIATIONS	viii
INTRODUCTION	1
ARGUMENT	3
I. EPA’S ALL CONDITIONS OF USE APPROACH IS UNLAWFUL.....	3
A. The “Best Reading” of TSCA Authorizes EPA to Evaluate Only Those Conditions of Use that Pose the Greatest Exposure Potential.	3
B. EPA’s Blanket Statements Do Not Provide a “Reasoned Analysis” Supporting its Changed Interpretation.	10
II. EPA’S WHOLE CHEMICAL APPROACH IS UNLAWFUL.....	10
A. The “Best Reading” of TSCA Authorizes EPA to Issue Risk Determinations Using a Use-by-Use Approach.	10
B. The Rule Deprives the Regulated Community of “Fair Warning” of Chemical Regulation.	14
III. INDUSTRY PETITIONERS’ PPE ARGUMENTS ARE RIPE FOR JUDICIAL REVIEW.....	15
A. The Rule’s Treatment of PPE is Ripe Now.	15
i. Fitness of the Issues for Judicial Decision	15
ii. Hardship of the Parties	16
B. Industry Petitioners’ Argument Is Not an As-Applied Challenge Because the Categorical Exclusion of PPE Applies to the Risk Evaluation Process in Every Instance.	17
IV. THE RULE’S TREATMENT OF PPE IS UNLAWFUL.....	20

A.	The Rule Is Inconsistent with TSCA’s Requirement for EPA to Consider All “Reasonably Available Information.”	20
B.	EPA Cannot Usurp Other Agencies’ Authority by Determining that Worker Protection Regulations Under a Separate Statutory Scheme Provide Inadequate Worker Protection.	21
CONCLUSION		23
CERTIFICATE OF COMPLIANCE		24
CERTIFICATE OF SERVICE		25

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Abbott Labs. v. Gardner</i> , 387 U.S. 136 (1967).....	15, 17
<i>Adams Fruit Co., Inc. v. Barrett</i> , 494 U.S. 638 (1990).....	21
<i>Am. Ass’n of Cosmetology Sch. v. Devos</i> , 258 F. Supp. 3d 50 (D.D.C. 2017).....	18
<i>Ass’n of Am. R.R.s v. Costle</i> , 562 F.2d 1310 (D.C. Cir. 1977).....	6
<i>Atl. Richfield Co. v. Dep’t of Energy</i> , 769 F.2d 771 (D.C. Cir. 1984).....	16
<i>Better Gov’t Ass’n v. Dep’t of State</i> , 780 F.2d 86 (D.C. Cir. 1986).....	17
<i>Butte Cnty. v. Hogen</i> , 613 F.3d 190 (D.C. Cir. 2010).....	10
<i>Cement Kiln Recycling Coal v. EPA</i> , 493 F.3d 207 (D.C. Cir. 2007).....	17
<i>Citizens United v. Fed. Election Comm’n</i> , 558 U.S. 310 (2010).....	17
<i>Clean Air Implementation Project v. EPA</i> , 150 F.3d 1200 (D.C. Cir. 1998).....	16
<i>George E. Warren Corp. v. EPA</i> , 159 F.3d 616 (D.C. Cir. 1998).....	16
<i>iTech U.S., Inc. v. Renaud</i> , 5 F.4th 59 (D.C. Cir. 2021).....	11, 12

<i>Loper Bright Enters. v. Raimondo</i> , 603 U.S. 369 (2024).....	3
<i>Nat’l Ass’n of Home Builders v. Army Corps of Eng’rs</i> , 417 F.3d 1272 (D.C. Cir. 2005).....	15, 16, 17, 19
<i>Nat’l Park Hosp. Ass’n v. Dep’t of Interior</i> , 538 U.S. 803 (2003).....	15
<i>Nat. Res. Def. Council v. EPA</i> , 643 F.3d 311 (D.C. Cir. 2011).....	17
<i>N.Y. Nurses Ass’n Benefits Fund v. Nyack Hosp.</i> 46 F.4th 97 (2d Cir. 2022)	5
<i>Safer Chemicals, Healthy Families v. EPA</i> 943 F.3d 397 (9th Cir. 2019)	18
<i>Sanjour v. EPA</i> , 56 F.3d 85 (D.C. Cir. 1995).....	18
<i>Singh v. Am. Honda Fin. Corp.</i> , 925 F.3d 1053 (9th Cir. 2019)	5
<i>Truck Trailers Mfrs. Ass’n v. EPA</i> , 17 F.4th 1198 (D.C. Cir. 2021).....	6
<i>United States Telecom Ass’n v. FCC</i> , 825 F.3d 674 (D.C. Cir. 2016).....	14
<i>United States v. Hayes</i> , 555 U.S. 415 (2009).....	8
<i>Vodenichar v. Halcon Energy Props., Inc.</i> , 733 F.3d 497 (3d Cir. 2013)	5
Statutes	
15 U.S.C. § 2602(4)	4, 6, 7
15 U.S.C. § 2604(h)(1)(A).....	9
15 U.S.C § 2605(a)	13

15 U.S.C. § 2605(b)(4)(A)	3, 4, 6, 11, 12
15 U.S.C. § 2605(b)(4)(D)	4, 7, 8
15 U.S.C. § 2605(b)(4)(F)	5, 20
15 U.S.C. § 2605(b)(4)(F)(ii)	13
15 U.S.C. § 2605(c)(1)	12
15 U.S.C. § 2605(i)	12, 13
15 U.S.C. § 2617(a)(1)(B)	13
15 U.S.C. § 2618(a)(1)	16

Regulations

40 C.F.R. § 702.39(f)(2)	15, 18, 20
--------------------------------	------------

Federal Register

Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act, 89 Fed. Reg. 37,028 (May 3, 2024) (codified at 40 C.F.R. Part 702, Subpart B)	1
---	---

Legislative Materials

162 Cong. Rec. 3511 (2016)	9, 10
H. Rep. No. 114-176 (2015)	22

Court Rules

Fed. R. App. P. 32	24
--------------------------	----

Other Materials

EPA Response to Public Comments (April 2024)	21
MERRIAM-WEBSTER DICTIONARY, <i>Expect</i> , https://www.merriam-webster.com/dictionary/expects (last visited Feb. 3, 2025)	7
<i>Top 10 Most Frequently Cited Standards</i> , OSHA, https://www.osha.gov/top10citedstandards (last visited Feb. 3, 2025)	21

GLOSSARY OF ABBREVIATIONS

ACC	American Chemistry Council
AFPM	American Fuel & Petrochemical Manufacturers
API	American Petroleum Institute
EPA	United States Environmental Protection Agency
MOU	Memorandum of Understanding
OSHA	Occupational Safety and Health Administration
PPE	Personal Protective Equipment
TCC	Texas Chemistry Council
TSCA	Toxic Substances Control Act

INTRODUCTION

Congress amended the Toxic Substances Control Act (“**TSCA**”) in 2016 to develop a comprehensive, step-by-step process for the U.S. Environmental Protection Agency (“**EPA**”) to conduct focused evaluations of select high-exposure uses of existing chemicals and determine which of those uses pose an unreasonable risk and which do not.¹ Congress also directed EPA to adopt a regulatory framework to implement each stage of this statutorily-mandated process.

As detailed in Industry Petitioners’ Opening Brief, EPA’s challenged Rule² establishes a framework that directly contradicts the one intended by Congress because it incorrectly interprets TSCA to require the agency to:

- 1) Evaluate *all* “conditions of use” of a chemical (“**All Conditions of Use Approach**”), rather than focusing on uses with the greatest exposure potential;
- 2) Issue a single Risk Determination for the entire chemical (“**Whole Chemical Approach**”), resulting in a binary determination of whether the chemical poses an unreasonable risk to human health or the

¹ The process includes: (1) Prioritization; (2) Risk Evaluation; and (3) Risk Determination (defined in Industry Petitioners’ Opening Brief). Risk Evaluation and Risk Determination are collectively referred to as the “**Risk Evaluation Process**”.

² Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act, 89 Fed. Reg. 37,028 (May 3, 2024) (codified at 40 C.F.R. Part 702, Subpart B) (“**Rule**”).

environment – despite the fact that some uses may pose unreasonable risks while others do not – rather than individual Risk Determinations for each condition of use (“**Use-by-Use Approach**”); and

- 3) Evaluate worker exposures without consideration of legally-required use of personal protective equipment (“**No-PPE Assumption**”).

EPA and Respondent-Intervenors defend the All Conditions of Use and Whole Chemical Approaches by reading TSCA in a piecemeal manner that disregards Congress’s command that EPA determine the conditions of use to evaluate based on their exposure potential and issue individualized Risk Determinations for each use.

Next, EPA wrongly contends that Industry Petitioners’ challenges to the No-PPE Assumption are not ripe for judicial review, even though the Rule makes clear that EPA *will apply* the No-PPE Assumption in *every* Risk Evaluation, rendering this a clear, and reviewable, issue. For the same reasons, EPA’s “as-applied” arguments are misplaced. Finally, the No-PPE Assumption fails on the merits because it disregards the reality of existing worker protection requirements (a risk factor that TSCA requires as part of EPA’s determination), exaggerates exposures and subsequent risk, and results in duplicative regulation and an overstep of agency authority.

In sum, the Rule disregards Congress’s intent for EPA to develop a regulatory framework that is consistent with TSCA’s mandates by allowing for a flexible, timely, unbiased, and science-based evaluation of existing chemicals. The Rule is arbitrary, capricious, unlawful, and cannot stand.

ARGUMENT

I. EPA’S ALL CONDITIONS OF USE APPROACH IS UNLAWFUL.

A. The “Best Reading” of TSCA Authorizes EPA to Evaluate Only Those Conditions of Use that Pose the Greatest Exposure Potential.

EPA and Respondent-Intervenors argue that the “best reading” of TSCA requires EPA to evaluate *all* uses of a chemical that meet the statutory definition of “conditions of use” when conducting Risk Evaluations. EPA Br. at 36–37; Resp. Int. Br. at 30;³ (quoting *Loper Bright Enters. v. Raimondo*, 603 U.S. 369 (2024)). However, employing “all relevant interpretive tools” of statutory construction establishes that the “best reading” of TSCA does *not* mandate the All Conditions of Use Approach. *Loper Bright*, 603 U.S. at 373.

TSCA requires EPA to conduct Risk Evaluations to assess whether a chemical presents unreasonable risk under “the conditions of use.” 15 U.S.C. § 2605(b)(4)(A). A determination of unreasonable risk under Section 2605(b)(4)(A) is TSCA’s statutory prerequisite to issue a regulation under Section 2605(a). EPA and

³ Citations to Briefs are to the top page number as filed.

Respondent-Intervenors focus on the placement of the word “the” before “conditions of use” to argue that TSCA does not permit EPA to evaluate only those conditions of use with the greatest exposure potential. *See* EPA Br. at 38; Resp. Int. Br. at 30 (citing 15 U.S.C. § 2605(b)(4)(A)). Notwithstanding EPA’s 180-degree change in interpretation from its prior rulemaking, this argument ignores TSCA’s plain text and structure.

A plain reading of TSCA dictates that the phrase “the conditions of use” in Section 2605(b)(4)(A) refers to the “conditions of use” identified by EPA early on in the Risk Evaluation Process during scoping. Critically, TSCA requires EPA to conduct scoping up front to guide the Risk Evaluation Process by identifying the “conditions of use” that EPA “expects to consider.” 15 U.S.C. § 2605(b)(4)(D). The term “the” before “conditions of use” in Section 2605(b)(4)(A) thus directs EPA to conduct its Risk Evaluation based on the conditions of use identified in the scope. Moreover, “conditions of use” is a defined term in Section 2602(4) that uses the word “or”, not “and”—“manufactured, processed, distributed in commerce, used, or disposed of” (emphasis added)—to delineate the relationship of those actions covered by the term. *Id.* § 2602(4).

The cases cited by EPA for the proposition that “the” before “conditions of use” means “all” actually support Industry Petitioners’ position. *See* EPA Br. at 38. Critically, the cited opinions concluded “the” *only* means “all” when there is no other

limiting language to consider. Thus, applying this concept to Section 2605(b)(4)(A), “the conditions of use” does not mean “all” given that Congress explicitly provided such limitations by requiring EPA to limit the “conditions of use” it “expects to consider” during scoping.⁴

For instance, EPA cites *N.Y. Nurses Ass’n Benefits Fund v. Nyack Hosp.*, for the holding that a trust agreement containing the term “the payroll and wage records” entitled trustees to *all* payroll and wage records, “not some subset.” *Id.* (citing 46 F.4th 97, 107 (2d Cir. 2022) (emphasis added)). However, EPA blatantly ignores that this decision also relied on the fact that “the language of the Trust Agreement [did not] limit the scope of the audit authority to some subset of the payroll and wage records.” *Nyack Hosp.*, 46 F.4th at 107. Here, the plain language of Section 2605(b)(4)(A) limits EPA’s evaluation to those conditions of use identified in the scope and demonstrates Congress’s intent to focus on priority uses of the chemical, just as would have occurred had there been limiting language in the agreement in *Nyack Hosp.*⁵

⁴ These conclusions also apply to EPA’s reference to similar sections of TSCA containing the phrase “the conditions of use.” EPA Br. at 38–39 (citing 15 U.S.C. § 2605(b)(4)(F)).

⁵ The other cases cited by EPA on this point also support Industry Petitioners’ position. EPA Br. at 38 (citing *Vodenichar v. Halcon Energy Props., Inc.*, 733 F.3d 497, 503, 506 (3d Cir. 2013); *Singh v. Am. Honda Fin. Corp.*, 925 F.3d 1053, 1068 (9th Cir. 2019)).

Respondent-Intervenors' reliance on *Ass'n of Am. R.R.s v. Costle*, 562 F.2d 1310 (D.C. Cir. 1977), is equally unpersuasive. Resp. Int. Br. at 30. In *Costle*, this Court concluded that the phrase "the equipment and facilities" included "all such equipment and facilities" in the context of EPA's duty to issue noise regulations. 562 F.2d at 1315. Critically, "[t]here [was] absolutely no indication . . . that Congress intended to vest discretion in the EPA to decide which of the equipment and facilities would be subject to regulation." *Id.* Therefore, *Costle* does not support Respondent-Intervenors' arguments because TSCA explicitly provides EPA with discretion to limit "the conditions of use" that it will evaluate. *See* 15 U.S.C. § 2605(b)(4)(A).

EPA attempts to limit its discretion by arguing that the phrase "as determined by the Administrator" in the definition of "conditions of use" does not allow it to exclude uses from evaluation. EPA Br. at 44 (quoting 15 U.S.C. § 2602(4)). However, read in context, the word "determined" provides EPA with discretion regarding which uses of a chemical should be considered "conditions of use" for purpose of Risk Evaluation. *See Truck Trailers Mfrs. Ass'n v. EPA*, 17 F.4th 1198, 1205 (D.C. Cir. 2021).

EPA next argues that its discretion is limited to determining how the chemical substance is "intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of," which does not allow it

to exclude uses. EPA Br. at 43. But this reading does not align with other provisions of TSCA that make clear that Congress provided EPA with discretion to exclude conditions of use from a Risk Evaluation. *See* 15 U.S.C. § 2605(b)(4)(D). The best reading of the phrase “as determined by the Administrator” must be read in a manner that mirrors that intent – requiring EPA to “determine” what constitutes a “condition of use,” and, if necessary, exclude certain uses.

After using its discretion to “determine” what constitutes a “condition of use” for the chemical, TSCA’s scoping section directs EPA to identify which of those conditions of use it “expects to consider.” *Id.* While not defined in TSCA, the plain meaning of “expects” is “to anticipate or look forward to the coming or occurrence of,” and thus provides EPA with choice and discernment regarding the conditions of use. MERRIAM-WEBSTER DICTIONARY, *Expect*, <https://www.merriam-webster.com/dictionary/expects> (last visited Feb. 3, 2025). Thus, a straightforward reading of Section 2605(b)(4)(D) permits EPA to exclude, during scoping, those conditions of use it does *not* anticipate evaluating.

Yet, EPA’s one-sided reading renders the scoping provision redundant and the phrase “expects to consider” superfluous. Section 2602(4) (“conditions of use” definition) already provides the bounds on how EPA should “determine” what constitutes conditions of use, and what does not. 15 U.S.C. § 2602(4). Specifically, *after* EPA determines what uses are “conditions of use,” Section 2605(b)(4)(D)

separately authorizes EPA to decide which uses it expects to consider and, by implication, which to exclude. *Id.* § 2605(b)(4)(D).

Moreover, EPA argues that the phrase “expects to consider” should be read as a “natural recognition” that “the conditions of use EPA identifies at the outset of the risk evaluation may not be the final set of conditions of use EPA considers in the risk evaluation.” EPA Br. at 47–48. This is a tacit acknowledgement by EPA that selection of the “conditions of use” involves some level of discretion, and may result in exclusion of certain uses from the initial scope and subsequent Risk Evaluation. Finally, the scoping provision does not give EPA “unbounded discretion” to select or ignore conditions of use. *Id.* at 48. As Industry Petitioners explained, the text and history show that Congress intended for EPA to focus on conditions of use that raise the greatest potential for exposure and subsequent risk when making scoping decisions. Ind. Pet. Br. at 34–35, 37–38.

Further, EPA’s interpretation of TSCA to mandate an All Conditions of Use Approach would “frustrate Congress’ manifest purpose” to create a streamlined Risk Evaluation Process. *United States v. Hayes*, 555 U.S. 415, 426–27 (2009). Requiring EPA to evaluate every “condition of use” of a chemical, even those that may be inherently safe or exceptionally unusual, would be an overwhelming endeavor and result in significant delays in every step of the Risk Evaluation Process. Congress did not intend to develop a review process that would put unnecessary pressures on

the agency and divert resources away from those uses that pose the greatest exposure potential.

EPA's and Respondent-Intervenors' remaining textual arguments are similarly unpersuasive. For instance, EPA argues that Section 5 of TSCA (which governs manufacturing and process notices for precommercial activities for new chemicals, appears in a different section of the statute, and is unrelated to Section 6 Risk Evaluations) illustrates how Congress would refer to "specific conditions of use," if it intended to exclude certain uses from Risk Evaluation. EPA Br. at 39 (citing 15 U.S.C. § 2604(h)(1)(A)). However, this provision relates to notice exemptions for the conditions of use that an individual manufacturer may identify in its own application for a new chemical substance and provides no insight regarding how Congress intended EPA to conduct Risk Evaluations for existing substances.

Finally, as discussed in Industry Petitioners' Opening Brief, TSCA's legislative history demonstrates Congress's intent for EPA to evaluate only those uses that raise the greatest exposure potential and subsequent risk. Ind. Pet. Br. at 37–38. EPA misconstrues the legislative history by arguing that Senator Vitter's statement supports a "'fit for purpose' approach [which] allows EPA to decide the conditions of use on which to focus the most analytical rigor" but does not permit the agency to "exclude" any uses. EPA Br. at 53–54 (quoting 162 Cong. Rec. S3511, S3519 (2016)). However, the Senator's clear explanation that TSCA directs EPA to

“determine the conditions of use that the Agency will address” and “focus chemical risk assessments on certain conditions of use” does not support EPA’s interpretation. 162 Cong. Rec. at S3519 (emphasis added). Thus, TSCA’s legislative history evidences Congress’s intent to provide EPA with discretion to determine which conditions of use to evaluate.

B. EPA’s Blanket Statements Do Not Provide a “Reasoned Analysis” Supporting its Changed Interpretation.

EPA’s defense of its changed interpretation from the 2017 rulemaking is vague and unsupported by the authorities it cites. EPA Br. at 54–55.

While the Preamble to the Rule listed four surface-level reasons for EPA’s decision to reverse course, EPA provided no discussion of how it reached its new interpretation. For instance, EPA did not elaborate on its “lessons learned” and how those lessons led to its changed interpretation. This conclusory explanation does not articulate a satisfactory explanation for the change. *See Butte Cnty. v. Hogen*, 613 F.3d 190, 194 (D.C. Cir. 2010) (“The agency’s statement must be one of ‘reasoning;’ it must not be just a ‘conclusion[.]’”).

II. EPA’S WHOLE CHEMICAL APPROACH IS UNLAWFUL.

A. The “Best Reading” of TSCA Authorizes EPA to Issue Risk Determinations Using a Use-by-Use Approach.

EPA and Respondent-Intervenors argue that the “best reading” of TSCA mandates the Whole Chemical Approach. EPA Br. at 56–57; Resp. Int. Br. at 46. In

doing so, they rely heavily on TSCA’s requirement for EPA to “determine whether a chemical substance presents an unreasonable risk of injury to health or the environment[.]” *Id.* (quoting 15 U.S.C. § 2605(b)(4)(A)). EPA argues that use of the word “a” before “chemical substance” is sufficient to show that a single Risk Determination represents the “best reading” of TSCA. *Id.* This argument amounts to an isolated reading of one portion of one provision of TSCA and therefore does not have merit. *See iTech U.S., Inc. v. Renaud*, 5 F.4th 59, 63 (D.C. Cir. 2021).

First, EPA’s dictation of Section 2605(b)(4)(A) omits language that makes clear that EPA must “conduct risk evaluations” (plural) to determine whether “a chemical substance” presents unreasonable risk, based on “the conditions of use.” 15 U.S.C. § 2605(b)(4)(A). Critically, this language contemplates multiple Risk Evaluations for a particular chemical and Risk Determinations that are specific to the conditions of use analyzed therein. Put simply, this provision authorizes the Use-by-Use Approach, and nowhere does Section 2605(b)(4)(A) (or TSCA as a whole) mandate or even suggest a Whole Chemical Approach.

EPA also argues that the Whole Chemical Approach is supported by TSCA’s instruction that “a determination by the Administrator under subsection (b)(4)(A) that a chemical substance does not present an unreasonable risk of injury to health or the environment” is considered a final agency action. *Id.* § 2605(i) (emphasis added). However, this argument ignores the plain language of this provision, which

explicitly references Section 2605(b)(4)(A), and dictates that a Risk Determination based on “the conditions of use” is a final agency action.

EPA continues to argue that “if Congress intended final agency action to be based on a use-by-use determination, Congress, at minimum, would have included the phrase ‘conditions of use’ in the final action provision.” EPA Br. at 58. However, Congress did exactly that by incorporating Section 2605(b)(4)(A), which contemplates the Use-by-Use Approach, into Section 2605(i). Taken together, these provisions make clear that EPA must base Risk Determinations on the conditions of use. The same logic applies to the Section setting forth the deadlines under which EPA must issue its Risk Determinations. *See* 15 U.S.C. § 2605(c)(1).

Next, EPA argues that TSCA’s state preemption section supports the Whole Chemical Approach because it is titled “*Chemical substances* found not to present an unreasonable risk or restricted,” rather than “*Conditions of use* found not to present an unreasonable risk or restricted.” EPA Br. at 65 (quoting 15 U.S.C. § 2617(a)(1)(B)). However, reliance on section headers is meaningless where the statutory text is plain. *iTech U.S., Inc.*, 5 F.4th at 65.

TSCA plainly states that state preemption applies to final agency actions under Section 2605(i) and final rules under Section 2605(a). 15 U.S.C. § 2617(a)(1)(B). Both Sections explicitly incorporate the requirement that EPA issue Risk Determinations “under the conditions of use.” *Id.* § 2605(b)(4)(A).

Accordingly, the plain text of TSCA—including the repeated incorporation of the phrase “the conditions of use” into all relevant Risk Determination provisions—mandates the Use-by-Use Approach.

Respondent-Intervenors argue the Use-by-Use Approach cannot be squared with Section 2605(b)(4)(F)(ii). Resp. Int. Br. at 47. However, that section requires EPA to *indicate* whether such aggregate or sentinel exposures “were considered” during the Risk Evaluation; it does not *mandate* such consideration. 15 U.S.C. § 2605(b)(4)(F)(ii). Therefore, TSCA recognizes that it may be appropriate for EPA to evaluate exposures from multiple conditions of use in the aggregate, but such an evaluation is not mandated in every instance.

Finally, Respondent-Intervenors argue that the Use-by-Use Approach would lead to an “absurd result” by requiring EPA to identify a new chemical for review following the conclusion of a Risk Evaluation for “each individual condition of use.” Resp. Int. Br. at 49. However, this is not what the statute requires. TSCA requires EPA to prioritize a chemical for review, conduct Risk Evaluations based on conditions of use selected by EPA, and issue Risk Determinations for each condition of use evaluated.

This statutorily-authorized Use-by-Use Approach will not lead to absurd results or delay the review process. It does the opposite by not obligating EPA to waste time and resources on crafting risk management rules around conditions of

use that do not pose an unreasonable risk (including those that may be inherently safe or exceptionally rare).

B. The Rule Deprives the Regulated Community of “Fair Warning” of Chemical Regulation.

The Whole Chemical Approach deprives the regulated community of “fair warning” regarding how EPA will ultimately regulate chemicals for which EPA makes an unreasonable Risk Determination. *See United States Telecom Ass’n v. FCC*, 825 F.3d 674, 736 (D.C. Cir. 2016) (FCC regulations satisfied due process where they provided factors to “guide the determination of what constitutes unreasonable interference”). Failure to provide “fair warning” is a due process violation. *See id.*

EPA argues that TSCA’s public notice and comment provisions provide the regulated community with “ample opportunities to meaningfully participate,” and therefore the Rule “do[es] not present any constitutional due process problems.” EPA Br. at 72. However, unlike the regulations at issue in *United States Telecom Ass’n*, the Rule provides no guidelines to inform the regulated community on EPA’s implementation of the Whole Chemical Approach. For example, the regulated community is left to wonder how EPA will address uses that are inherently safe during risk management. Without such information, the Rule fails to provide fair warning regarding how EPA’s arbitrary Whole Chemical Approach will impact industry.

III. INDUSTRY PETITIONERS' PPE ARGUMENTS ARE RIPE FOR JUDICIAL REVIEW.

A. The Rule's Treatment of PPE is Ripe Now.

Industry Petitioners' challenge to the Rule's No-PPE Assumption is ripe for review *now*. Determining whether administrative action is ripe for judicial review involves an evaluation of “(1) the fitness of the issues for judicial decision and (2) the hardship to the parties of withholding court consideration.” *Nat'l Park Hosp. Ass'n v. Dep't of Interior*, 538 U.S. 803, 808 (2003) (citing *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967)).

i. Fitness of the Issues for Judicial Decision

Under the first prong, this Court considers whether an issue is “purely legal, whether consideration of the issue would benefit from a more concrete setting, and whether the agency's action is sufficiently final.” *Nat'l Ass'n of Home Builders v. Army Corps of Eng'rs*, 417 F.3d 1272, 1281 (D.C. Cir. 2005).

First, there is no serious dispute that Industry Petitioners' PPE argument is a “purely legal” issue. *Id.* This Court has “repeatedly held that claims that an agency's action is arbitrary and capricious or contrary to law present purely legal issues.” *Id.* at 1281–82.

Next, judicial review of the No-PPE Assumption would not “benefit from a more concrete setting.” *Id.* The Rule explicitly states that EPA “will not consider exposure reduction” based on assumed use of PPE. 40 C.F.R. § 702.39(f)(2)

(emphasis added). Therefore, it is clear that the No-PPE Assumption will apply to the Risk Evaluation Process in every instance. Moreover, all of the facts needed for judicial review were before EPA when it finalized the Rule, and EPA's action "necessarily stands or falls on that administrative record and" an analysis of TSCA. *Nat'l Ass'n of Home Builders*, 417 F.3d at 1282. Therefore, this Court does not require any "future factual developments" to add to the "present understanding of the effect" that the Rule will have on Industry Petitioners. *See George E. Warren Corp. v. EPA*, 159 F.3d 616, 621–22 (D.C. Cir. 1998); *Atl. Richfield Co. v. Dep't of Energy*, 769 F.2d 771, 783 (D.C. Cir. 1984).

Finally, EPA's action is "sufficiently final" because it is a final rule promulgated under TSCA. *Clean Air Implementation Project v. EPA*, 150 F.3d 1200, 1205 (D.C. Cir. 1998). Accordingly, Industry Petitioners' PPE arguments satisfy the first prong of the ripeness analysis.

ii. Hardship of the Parties

The second prong of the ripeness doctrine—"hardship to the parties of withholding court consideration"—is not at issue here. *Nat'l Ass'n of Home Builders*, 417 F.3d at 1281. Congress required that challenges to TSCA rules be brought within 60 days of promulgation. 15 U.S.C. § 2618(a)(1). Therefore, "because Congress has emphatically declared a preference for immediate review with respect to [TSCA] rulemaking," the Court has "no need to consider . . . the

hardship to the parties of withholding review.” *Nat. Res. Def. Council v. EPA*, 643 F.3d 311, 320 (D.C. Cir. 2011); *accord Cement Kiln Recycling Coal. v. EPA*, 493 F.3d 207, 215 (D.C. Cir. 2007).

But, even if this Court requires a showing of hardship, “the impact of the administrative action” on Industry Petitioners, “in conducting their day-to-day affairs,” weighs strongly in favor of Industry Petitioners’ “interest in immediate review.” *Better Gov’t Ass’n v. Dep’t of State*, 780 F.2d 86, 92 (D.C. Cir. 1986); Declaration of ACC at 8–9.

Finally, when a rulemaking creates a categorical approach for all future rulemakings, that categorical approach is ripe for review. *Abbott Labs.*, 387 U.S. at 150. Accordingly, the Rule’s categorical approach to apply the No-PPE Assumption to every Risk Evaluation is ripe for review *now*.

B. Industry Petitioners’ Argument Is Not an As-Applied Challenge Because the Categorical Exclusion of PPE Applies to the Risk Evaluation Process in Every Instance.

EPA’s assertion that Industry Petitioners’ PPE arguments are “as-applied” is similarly unpersuasive. EPA Br. at 72. At the outset, “the distinction between facial and as-applied challenges is not so well defined that it has some automatic effect or that it must always control the pleadings and disposition in every case involving a constitutional challenge.” *Citizens United v. Fed. Election Comm’n*, 558 U.S. 310, 331 (2010). Additionally, “in the administrative-law context, the distinction between

facial and as-applied challenges is even more elusive and has little analytical value.”

Am. Ass’n of Cosmetology Sch. v. Devos, 258 F. Supp. 3d 50, 66 n.6 (D.D.C. 2017).

The “as-applied” concept is inappropriate for this case. “As-applied” challenges are most commonly applicable where the Court is being asked to “declare the challenged statute or regulation unconstitutional on the facts of the particular case.” *Sanjour v. EPA*, 56 F.3d 85, 92 n.10 (D.C. Cir. 1995). Here, by contrast, Industry Petitioners need not challenge the Rule’s treatment of PPE “as applied” to a specific factual situation. Rather, Industry Petitioners contend that the Rule’s treatment of PPE is contrary to law and outside the scope of EPA’s authority because it ignores TSCA’s mandate and Congressional intent. To that end, EPA’s reference to *Safer Chemicals, Healthy Families v. EPA* is misplaced. 943 F.3d 397 (9th Cir. 2019).

In *Safer Chemicals*, the Ninth Circuit concluded “that Petitioners’ challenge . . . is not justiciable because it is not clear, due to the ambiguous text of the Risk Evaluation Rule, whether the Agency will actually conduct risk evaluations in the manner Petitioners fear.” *Id.* at 412. Here, the Rule unambiguously states that “EPA will not consider exposure reduction based on assumed use of [PPE].” 40 C.F.R. § 702.39(f)(2) (emphasis added). Thus, the plain text of the Rule mandates that the No-PPE Assumption apply to every Risk Evaluation.

Even if this Court considers the “facial/as-applied” distinction, the legality of “the challenged feature” of the Rule’s treatment of PPE “will not change from case to case” because EPA’s “faithful application” of the Rule’s treatment of PPE would carry the agency beyond its statutory mandate. *Nat’l Ass’n of Home Builders*, 440 F.3d at 464–65. EPA may not assume noncompliance with existing regulations and simultaneously usurp authority to regulate workplace protection from agencies and programs tasked with such.

EPA’s attempts to soften its stance on the treatment of PPE are inconsistent with the Rule. According to EPA, the Rule “stated that [EPA] would consider reasonably available information regarding personal protective equipment use and efficacy in assessing exposure but would not rely on assumptions of such use or efficacy when making a risk determination.” EPA Br. at 76. Yet, the text of the Rule is clear that EPA “will not” assume the use of PPE when conducting Risk Evaluations. This regulatory mandate will result in concrete, particularized harm to Industry Petitioners and requires no further factual development.

IV. THE RULE'S TREATMENT OF PPE IS UNLAWFUL.

A. The Rule Is Inconsistent with TSCA's Requirement for EPA to Consider All "Reasonably Available Information."⁶

EPA argues that Industry Petitioners claimed that TSCA requires EPA to assume that PPE "is always used by all workers" in an effective manner. EPA Br. at 77. However, that is not Industry Petitioners' position. Rather, Industry Petitioners argue that EPA is impermissibly giving itself license to assume that PPE is *not* used in the workplace, no matter the circumstances. This assumption is divorced from reality and is inconsistent with TSCA's requirements for EPA to consider all "available information on hazards and exposures for the conditions of use of the chemical substance" and "likely duration [and] intensity . . . of exposures." 15 U.S.C. § 2605(b)(4)(F).

Industry Petitioners and EPA agree that "reasonably available information" includes information regarding PPE and existing regulatory requirements. However, the Rule is problematic because it allows EPA to disregard certain "reasonably available information," such as existing workplace regulations mandating PPE use.

EPA states that, where information regarding occupational control measures is made available, it "will take into account" such measures "in the exposure

⁶ Labor Petitioners argue that TSCA does not permit consideration of PPE in Risk Evaluations. However, for the reasons set forth herein and in Industry Petitioners' Opening Brief, this is an incorrect interpretation of TSCA.

assessments.” EPA Response to Public Comments at 31, JAxix. But EPA failed to explain how it will take these measures into account when the Rule mandates that it “will not consider exposure reduction” based on assumed use of PPE. EPA cannot have its cake and eat it too.

B. EPA Cannot Usurp Other Agencies’ Authority by Determining that Worker Protection Regulations Under a Separate Statutory Scheme Provide Inadequate Worker Protection.

EPA argues that “the availability, efficacy, and reliability of use” of PPE varies widely, but points to minimal concrete evidence to that effect. EPA Br. at 76. Even if this is true, EPA lacks authority to assume noncompliance with existing worker protection regulations. In fact, EPA acknowledges that many “companies likely have well-established occupational control measures in place.” EPA Response to Public Comments at 31, JAxix. Furthermore, EPA cannot override OSHA’s authority by determining that their regulations provide inadequate worker protection. *Adams Fruit Co., Inc. v. Barrett*, 494 U.S. 638, 650 (1990).

One of the only sources EPA cites regarding non-use of PPE is OSHA’s *Top 10 Most Frequently Cited Standards*.⁷ However, if EPA takes issue with compliance with or enforcement of OSHA or other regulatory regimes, the agency administering those regimes is responsible for resolving those issues. EPA does not have the

⁷ *Top 10 Most Frequently Cited Standards*, OSHA, <https://www.osha.gov/top10citedstandards> (last visited February 3, 2025).

authority under TSCA to overreach into other regulatory programs for which it does not have subject matter expertise. Allowing EPA to do so via the Rule's treatment of PPE distorts Risk Determinations, disregards TSCA and Congressional intent by failing to defer to other agencies or regulatory programs, and results in duplicative, confusing regulation that harms Industry Petitioners. *See* H. Rep. No. 114-176, at 28–29 (2015) (encouraging EPA to make “decisions that avoid confusion, complication, and duplication” and to “respect the experience of, and defer to other agencies that have relevant responsibility such as the Department of Labor in cases involving occupational safety”).

CONCLUSION

For the foregoing reasons and those set forth in Industry Petitioners' Opening Brief, Industry Petitioners respectfully request this Court vacate the Rule as arbitrary, capricious, not in accordance with law, and in excess of EPA's statutory authority.

Respectfully submitted,

/s/ Rafe Petersen

Rafe Petersen
Meaghan Colligan Hembree
HOLLAND & KNIGHT LLP
800 17th Street N.W.
Suite 1100
Washington, D.C. 20006
Rafe.Petersen@hklaw.com
Meaghan.Colligan@hklaw.com
Tel.: (202) 419-2481

*Attorneys for Petitioners Texas Chemistry
Council and American Chemistry Council*

/s/ David Y. Chung

David Y. Chung
Warren Lehrenbaum
CROWELL & MORING LLP
1001 Pennsylvania Avenue N.W.
Washington, D.C. 20004
DChung@crowell.com
WLehrenbaum@crowell.com
Tel.: (202) 624-2587

*Attorneys for Petitioners American Fuel &
Petrochemical Manufacturers and American
Petroleum Institute*

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(g), I hereby that this brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) and the Court's order dated September 9, 2024 because it contains 4,883 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f), according to the count of Microsoft Word.

I further certify that this brief complies with the typeface and type-style requirements of Fed. R. App. P. 32(a)(5) and (6) because it has been prepared in 14-point Times New Roman font.

/s/ Rafe Petersen
Rafe Petersen

/s/ David Y. Chung
David Y. Chung

CERTIFICATE OF SERVICE

I hereby certify that on this 3rd day of February, 2025, the foregoing Reply Brief of Petitioners has been served on all registered counsel through the Court's electronic filing system.

/s/ Rafe Petersen

Rafe Petersen

/s/ David Y. Chung

David Y. Chung